suggested, I have not cancelled the old embodiments and have retained the corresponding claims and drawings in the file. I have also corrected the text in order to correspond to the drawings and have added two new sheets of drawings. Drawing No.7 demonstrates the tilting of the solid ring of the first and second embodiment and drawing No 8 demonstrates the change of the distance between the solid ring and the base of the vaginal delineation andoccluding device, when the four legs are telescopic, spring loaded and a pressure is applied on the solid ring.

BACKGROUND OF THE INVENTION

Field of the invention

The present invention relates generally to a medical device. More particularly the present

Invention relates to a vaginal occlusion and self-adjusting delineation attachment for use with the uterine mobilizer.

Background Art

Hysterectomy is a gynaecological surgical procedure for removal of the uterus, partially or totally. There are different types of hysterectomies. Total abdominal hysterectomy (TAH), supracervical Hysterectomy (S.H.),vaginal hysterectomy, total laparoscopic hysterectomy (TLH), laparoscopically assisted vaginal hysterectomy (LAVH), laparoscopic supracervical hysterectomy (L.S.H.). TLH, L.S.H. and LAVH have become more popular among surgeons, because these approaches are less invasive, the patients have less pain and shorter hospital stay than after TAH and supracervical hysterectomy. Unless medical indications require TAH (such as in the case of tumour removal and the associated need to avoid cell spillage), vaginal, TLH and LAVH are usually viewed as more preferable because each is less invasive when compared to major abdominal surgery. Thus, TLH and LAVH approaches usually result in shorter hospitalization and recovery times.

Difficulties arise in TLH, however, in identification of the fornix of the vagina. Another technicality is leakage of carbon dioxide from the peritoneal cavity when the vagina is opened laparoscopically.

Another problem, not appropriately addressed in the prior art, is that human bodies vary considerably. Any vaginal insertion device for surgical procedures must, therefore, be adjustable. Such devices are, preferably, self-adjusting.

There is therefore a need for a vaginal delineation device, attachable to a uterine mobilizer that also provides occlusion to the vagina to disallow leakage of carbon dioxide. There is a further need for a vaginal delineation and occluding device that is adjustable, and as self-adjusting as possible.

BRIEF SUMMARY OF THE INVENTION

An object of the present invention is to provide a vaginal delineation and occluding device for use in gynaecological laparoscopic surgical procedures which is an attachment to a uterine mobilizer, such as the Valtchev uterine mobilizer, and is self adjusting to various lengths of cervixes and angles of fornices.

The present invention is a device that inserts and locks into a uterine mobilizer, the device comprises a ring that adjusts in angle. The ring is made to bear against the vaginal fornix, conforming to its angle and providing delineation of that part of the vagina for identification thereof.

In a second embodiment, the ring is also self-adjusting as to the distance from the uterine mobilizer, to accommodate varying lengths of the cervix. This is effected by pivotally mounting the ring onto four telescopic rods or legs, all spring loaded.

A third embodiment of the present invention is configured like a cup with a rigid ring, pivotally attached at the top of the cup. Again, the pivotal attachment provides accommodation for varying angles of the fornix.

Another object is to provide an occluder to prevent leakage of carbon dioxide from the peritoneal cavity when the vagina is opened laparoscopically. An enlarged portion of an extension at the base of the vaginal delineator, said extension being inserted into the uterine mobilizer, is made to receive a diaphragm made of an elastic material such as plastic, silicon, nylon, etc. The diaphragm obstructs the vaginal cavity toward the outside of the vaginal delineator, preventing leakage of carbon dioxide from the peritoneal cavity.

In the third embodiment of the invention, the cup is the occluding apparatus as well as the structure on which the variable-angle, rigid ring is mounted.

Other objects, advantages and novel features of the present invention will become apparent from the following detailed description of the invention when considered in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

Fig.1 is a side elevation view of a uterine mobilizer and vaginal delineating and occluding device;

Fig.2a is a first side elevation view of a first embodiment of the vaginal delineating and occluding device;

Fig2b is a plan view from the top of the first embodiment of the vaginal delineating and occluding device;

Fig2c is a second side elevation view of the first embodiment of the vaginal delineating and occluding device;

Fig2d is a plan view from the bottom of the first embodiment of the vaginal delineating and occluding device;

Fig.2e is a side elevation view of a telescopic arm for the vaginal delineating and occluding device;

Fig.3a is a plan view of a diaphragm for the vaginal delineating and occluding device;

Fig.3b is a cross section ~~top view~~ of a diaphragm for the vaginal delineating and occluding device;

Fig.4a is a plan view from the top of a second embodiment of the vaginal delineating and occluding device;

Fig.4b is a side elevation view of the second embodiment of the vaginal delineating and occluding device;

Fig.4c is a plan view from the bottom of the second embodiment of the vaginal delineation and occluding device;

Fig.4d is a first side elevation view of a telescopic spring loaded arm for the second embodiment vaginal delineating and occluding device, where the spring is placed between the outer telescopic arm and the distal arm.

Fig.4e is a second side elevation view of a telescopic spring loaded arm for the second embodiment vaginal delineating and occluding device, where the spring is placed into the cavity of the outer telescopic arm.

Fig.5a is a side elevation view of a third embodiment of the vaginal delineating and occluding device minus a solid ring to clearly show angles;

Fig.5b is a cutaway side elevation view of a third embodiment of the vaginal delineating and occluding device;

Fig.5c is a side elevation view of a third embodiment of the vaginal delineating and occluding device, with a pivotally attached solid ring;

Fig.5d is a plan view from the top of a third embodiment of the vaginal delineating and occluding device;

Fig.6 is a cutaway view of a female pelvis, the vaginal delineating and occluding device being ~~mounted on~~ inserted and locked in a uterine mobilizer and inserted into the vagina;

Fig.7 (new sheet) is the third side view of the first embodiment of the vaginal delineation and occluding device showing the tilting of the solid ring;

Fig. 8 (New sheet) is the side elevation view of the second embodiment of the vaginal delineation and occluding device showing the change of the distance between the base of the vaginal delineation and occluding device and the solid ring when pressure is applied on the solid ring.

DETAILED DESCRIPTION OF THE INVENTION

A first, preferred embodiment of a vaginal delineating and occluding device **100** is shown in **Fig.1** along with a uterine mobilizer **110** as disclosed in **U.S.Patent 5,562,679** which is hereby incorporated by reference. The vaginal delineating and occluding device **100** is ~~attached to~~ inserted and locked in the head **120** of the uterine mobilizer **110** shown in Fig. 6. The device shown in detail in **Figs.2a-e** is a first embodiment of the vaginal delineating and occluding device **100** of the present invention. A base **205** has an extension **250** for insertion and locking into the head **120** of the uterine mobilizer **110** ~~.and is locked therein~~. The proximal end **215** of the base **205** is for attaching obturators of various lengths. A solid metal ring **200** is pivotally attached to four legs **210, 230,** via pins 220 and 270. The distal ends of a first pair of solid legs **210** are firmly affixed to the base **205**~~.via pins 220 about which the ring 200 may pivot~~. The ring **200** is permitted to pivot about 20° in both directions from a plane perpendicular to a longitudinal axis of the base **205 (Fig.7)**. This pivoting permits the accommodation of various angles of the vaginal fornix **620** (see **Fig.6**). The first pair of legs **210** is preferably of a single

piece, solid throughout. The second pair of legs **230** is telescopic and comprises a plurality of parts as detailed in **Fig.2e**. A proximal ~~distal~~ end of a ~~secure~~ distal arm **255** engages a pin **280** to which an inner telescoping arm **265** is pivotally attached. The inner telescoping arm **265** slides into the distal end of an outer telescoping arm **260.** The outer telescoping arm ~~is~~ **260** is pivotally attached to the ring **200** at its proximal end by a pin **270.** The outer telescoping arm **260** is a hollow tube to receive the proximal end of the inner telescoping arm **265.** A diaphragm **225** of elastic material such as plastic, nylon, silicon, etc. is shown in **Figs.3a and 3b.** Its use is to obstruct the vagina ~~for the prevention of~~ and does not allow a flow in any direction ~~carbon dioxide leakage from the peritoneal cavity~~ when the vagina is opened laparoscopically. The diaphragm **225** has a hole **300** in its center through which an enlarged portion **275** of the base **205** of the vaginal delineating and occluding device **100** passes ~~.and helps secure the diaphragm 225.~~ When the distal end of the base **205** is inserted in the uterine mobilizer **110,** the diaphragm **225** is held securely between the base **205** and the head of a mobilizer **110,** preventing flow in any direction. Various sizes of diaphragms **225** may be supplied to fit a variety of patients. ~~About the circumference of the diaphragm 225 is an enlarged portion 310. A center annulus 320 is thicker than a center membrane 330.~~ The rim 310 and the annulus 320 are thicker than a membrane 330, Fig.3 a-b

A second embodiment of the vaginal delineating and occluding device **100** is shown in **Figs.4a-e.** In this embodiment all the legs **410** are made as the telescoping legs **410,** described above. In addition, a spring **440** applies a force to separate the solid ring **200** away from the base **205**. The spring **440** may bear directly on the ~~secure~~ distal arm **255** and the outer telescoping arm **260** as shown in **Fig.4d;** or it may bear on the proximal end of the inner telescoping arm **265** and the ~~solid ring 200~~ proximal end of the hollow part of the outer telescopic arm as shown in **Fig.4e**. In this embodiment, the distance ~~location~~ of the solid ring **200** relative to the base **205** is adjustable, when a pressure **F** is applied to the solid ring which ~~to~~ accommodates various lengths of the cervix. (see Fig. 8)

A third embodiment of the present invention is shown in **Figs.5a-d.** Here, a cup **500** is illustrated the rim of which has a slope in two opposite directions, the slope having an angle, 0,where 0 is about 15°. This cup **500** is inserted and locked ~~attached~~ in the same way into the head **120** of the uterine mobilizer **110** via an extension **250**. Pivotally attached at the top ~~if~~ of the cup **500** is a rigid ring **510**, preferably constructed of a metallic material. The rigid ring **510** is pivotally attached ~~ot~~ by pins **520** that permit the ring to tilt through the angle,0, as far as the rim of the cup **500,** again, about 15°. The view in **Fig.5a** is intentionally without the ring **510** to show the angle 0.

The ring **510** bears against the fornix **620,** the cup **500** acts to occlude the vagina, replacing the diaphragm **225** of the previous embodiments. The vaginal delineating and occluding device **100** of the first embodiment is shown in use in **Fig.6.** The vaginal delineating and occluding device **100** is inserted into a vagina **610** inserted and locked in the uterine mobilizer **110** until the ring **200** of the vaginal delineating and occluding device **100** rests against the vaginal fornix **620.**

The above embodiments are the preferred embodiments, but this invention is not limited thereto. It is, therefore, apparent that many modifications and variations of the present invention are possible in light of the above teachings. It is, therefore, to be understood that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described.